K100094

"510(k) Summary"

MAR 11 2010

510(k) Owner Name	Carestream Health, Inc.
510(k) Owner Address	150 Verona Street Rochester, New York 14608
510(k) Owner Phone	585 627-6543
510(k) Owner Fax	585 454-1894
Contact Name & Info	John Pardo Director, Regulatory Affairs and Quality Systems john.pardo@carestreamhealth.com
Date Summary Prepared	January 5, 2010
Device Trade Name	CARESTREAM Image Suite
Device Common Name	CARESTREAM Image Suite
Classification Name	System, Image Processing, Radiological
Regulation Name	Picture Archiving and Communication System
Device Class	Class II
Device Code	LLZ
Regulation Number	21 CFR 892.2050, Picture Archiving and Communications System
Predicate Device	K083673 - Device Name: CARESTREAM PACS V11 K060137 - Device Name: Kodak Eclipse Image Processing Software

Device Description

CARESTREAM Image Suite is a stand-alone, self-contained radiographic imaging system designed to provide a low-cost platform to manage medical images, reports, patient/exam information and workflow in small clinics. The system performs capture, processing, review, archiving, and printing of radiographic images as well as report writing and printing and is designed to run on a PC workstation. The CARESTREAM Image Suite is designed to be simple and intuitive to both use and service.

CARESTREAM Image Suite is designed as a hardware-independent system and may be interfaced with verified and validated image acquisition devices from both Carestream Health and 3rd party vendors, Carestream Health PACS system, and other 3rd party PACS systems. The system will acquire an image from either a DirectView Classic CR or a Point-of-Care 140/145 or 360 CR and be PC and monitor independent.

Intended Use

The CARESTREAM Image Suite System is an image management system whose intended use is to receive, process, review, display, print and archive images and data from CR and DR modalities. This excludes mammography applications in the United States.

Comparison of Technological Characteristics

The subject device and predicate devices use the same technical design base. The CARESTREAM Image Suite supports web registration, web viewer, PoC and Classic CR scanner integration, report, CD export, image processing and long term image storage. The design is based on current Carestream technology with the image processing modules using the existing KODAK Eclipse Image Processing Software product without any modifications to the software responsible for image processing.

Discussion of Testing

Performance testing was conducted to verify the design output met the design input requirements and to validate the device conformed to the defined user needs and intended uses. Nonclinical testing was conducted under simulated use conditions. Predefined acceptance criteria was met and demonstrated that the device is as safe and as effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAR 11 2010

Mr. John Pardo
Director, Regulatory Affairs and Quality Systems
Carestream Health, Inc.
150 Verona Street
ROCHESTER NY 14608

Re: K100094
Trade/Device Name: CARESTREAM Image Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 3, 2010
Received: March 4, 2010

Dear Mr. Pardo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100094

Device Name: CARESTREAM Image Suite

Indications for Use: CARESTREAM Image Suite is an image management system whose intended use is to receive, process, review, display, print and archive images and data from all imaging modalities. This excludes mammography applications in the United States.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100094